

35 U.S.C. §112 Rejections

Claims 63-121 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. These rejections are respectfully traversed and are addressed separately below:

Regarding claim 63, it is respectfully pointed out that the soft segment is formed from at least one of a macrodiol, a macrodiamine, and a compound of formula (I). The term “at least one of” is reasonably interpreted to mean that any one or more of a macrodiol, a macrodiamine, and a compound of formula (I) can be used to form the soft segment. Additionally, the chain extender includes the compound of formula (I) and optionally a second chain extender. Applicant respectfully points out that the last three lines of the claim have been deleted to remove any indefiniteness. As such, claim 63 recites a polyurethane-urea elastomeric composition that includes a soft segment and a hard segment. The hard segment is formed from a diisocyanate and a chain extender, wherein the chain extender includes a compound of formula (I). The soft segment is formed from at least one of a macrodiol, a macrodiamine, and a compound of formula (I).

Regarding claims 63, 104, 111, and 112, the formula (I) has been amended to remove any confusion. Specifically, formula (I) illustrates R₅ bonded directly to the nitrogen atom.

Regarding claim 111, the formula recited therein is correctly identified as formula (I). As recited in claim 63, the chain extender includes the compound of formula (I); the compound of formula (I) can also be used to form the soft segment.

Claim 72 has been amended such that 1,3-diaminocyclohexane is spelled correctly.

Regarding claims 73 and 74, it is respectfully pointed out that the claims recite the molar percentage of the compound of formula (I).

Regarding claim 76, it is respectfully pointed out that “isomer thereof” refers to any one or more of the diisocyanates recited therein.

Regarding claims 82, 83, 87, and 91, it is respectfully pointed out that PDMS refers to polydimethylsiloxane. Claims 82, 83, 87, and 91 have been amended accordingly.

Regarding claim 102, the trade name POLAMINE 650 is an amine terminated

polytetramethyleneoxide. Claim 102 has been amended accordingly.

Regarding claims 86, 93, 100, 104, 111, and 112, Examiner asserts that the term “about” renders the claims indefinite and states that it cannot be determined exactly which compounds are defined or encompassed by the structure. Although Applicant maintains that the term “about” does not render the claim indefinite, claims 86, 93, 100, 104, 111, and 112 have been amended to remove the term “about” in order to facilitate prosecution of the present invention.

Regarding claims 96 and 97, the claims have been amended to reflect the proper dependencies.

Regarding claim 98, the Examiner asserts that the term “based” renders the claim indefinite, and states that it is unclear to what extent the polycarbonates is “based” on or derived from silicon. Applicant respectfully points out that a silicon based polycarbonate macrodiol is a polycarbonate macrodiol that includes silicon. This silicon based polycarbonate (i.e., polycarbonate that includes silicon) is prepared by reacting an alkylene carbonate with 1,3-bis(4-hydroxybutyl)-1,1,3,3-tetramethyldisiloxane (BHTD). Applicant maintains that the meaning is clear and definite.

Regarding claims 104, 109, and 112, the Examiner asserts that the last part of the claims is unclear and indefinite. Applicant respectfully points out that the language forms part of a Markush group. If the Examiner maintains that the claims are still unclear and indefinite, Applicant respectfully invites Examiner to suggest alternative language to place the claims in condition for allowance.

Claims 111 and 121 have been amended to correct the typographical errors. Specifically, the relevant semi-colons have been replaced with commas.

Regarding claims 113-117, the Examiner asserts that the terms “resistant,” “improved” and “useful as” do not further patentably limit or distinguish the claims. Claims 113-116 have been canceled and claim 117 has been amended such that the term “useful as” has been removed.

Applicant believes claims 63-121 are definite and particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Accordingly, withdrawal of the 35 U.S.C. § 112, second paragraph, rejection is earnestly requested.

Claims 81-103 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant respectfully traverses this rejection.

Specifically, the Examiner states that claims 81, 89, 90, 96, and 97 fail to specify the type of molecular weight or how it has been determined. The molecular weights recited in claims 81, 89, 90, 96, and 97 are the number average molecular weights and not the weight average molecular weights. The claims have been amended accordingly.

Applicant believes that claims 81-103 contain subject matter which is described in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Accordingly, withdrawal of the 35 U.S.C. § 112, first paragraph, rejection is earnestly requested.

35 U.S.C §103 Rejection

Claims 63-121 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Szycher et al. (U.S. 5,863,627) or WO 98/13405 or JP 4-248826, each in view of Li et al. (U.S. 5,221,724) and Ohtaki et al. (U.S. 5,861,085). This rejection is respectfully traversed.

Szycher et al. (U.S. 5,863,627)

The '627 patent discloses polycarbonate polyurethanes having internal polysiloxane segments. See, Abstract.

WO 98/13405

The '405 patent discloses a polyurethane elastomeric composition that includes a soft segment derived from at least one polysiloxane macrodiol and at least one polyether and/or polycarbonate macrodiol. The '405 patent, however, does not disclose a silicon-containing diamine of formula (I).

JP 4-248826

JP 4-248826 discloses polyurethane or polyurethane-urea prepared from a polysiloxane with terminal hydroxy or amino groups, a diisocyanate and a polyether polyol containing a tertiary amino group in the backbone of the polyether polyol.

Li et al. (U.S. 5,221,724)

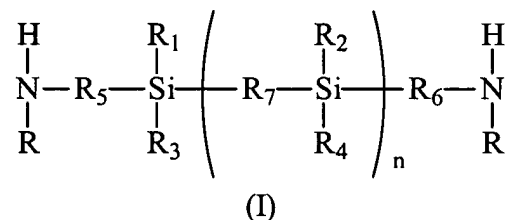
The '724 patent discloses hydrophilic segmented polyurea urethane and polyurea block copolymers that include an organic diisocyanate-modified amine-terminated polysiloxane soft segment. See, column 2, lines 39-42. The soft segment comprises an oligomer that includes the reaction product of an organic diisocyanate and an amine-terminated polysiloxane of the formula recited therein.

Ohtaki et al. (U.S. 5,861,085)

The '085 patent discloses a method for purifying 1,3-bis(3-aminopropyl)-1,1,3,3-tetraorganodisiloxane. See, e.g., Abstract.

Claims 63-108, 111-112, and 117-124

Claim 63 recites a polyurethane-urea elastomeric composition comprising a soft segment and a hard segment, wherein the soft segment is formed from at least one of a macrodiol, a macrodiamine, and a compound of formula (I):



wherein

R is hydrogen or an optionally substituted straight chain, branched or cyclic, saturated or unsaturated hydrocarbon radical;

R_1 , R_2 , R_3 , R_4 , R_5 and R_6 are each independently hydrogen or an optionally substituted straight chain, branched or cyclic, saturated or unsaturated hydrocarbon radical;

R_7 is a divalent linking group or an optionally substituted straight chain, branched or cyclic, saturated or unsaturated hydrocarbon radical; and

n is an integer of 1 or greater;

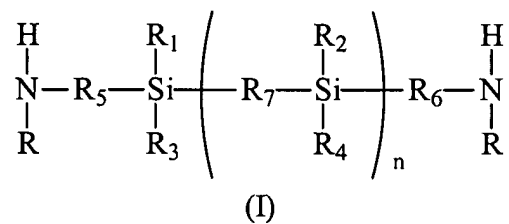
wherein the macrodiol is a polysiloxane macrodiol, a polyether macrodiol, a polycarbonate macrodiol, or a mixture thereof;

and wherein the hard segment is formed from:

- (i) a diisocyanate; and
- (ii) a chain extender comprising the compound of formula (I) and optionally a second chain extender.

Claim 104 recites a polyurethane-urea elastomeric composition comprising a soft segment and a hard segment, wherein the soft segment is formed from:

- (i) a macrodiol comprising a polysiloxane macrodiol and a polyether macrodiol;
- and wherein the hard segment is formed from:
- (ii) a diisocyanate; and
 - (iii) a chain extender selected from the group consisting of a compound of formula (I):



wherein

R is hydrogen or an optionally substituted straight chain, branched or cyclic, saturated or unsaturated hydrocarbon radical;

R_1 , R_2 , R_3 , R_4 , R_5 and R_6 are each independently hydrogen or an optionally substituted straight chain, branched or cyclic, saturated or unsaturated hydrocarbon radical;

R_7 is a divalent linking group or an optionally substituted straight chain, branched or cyclic, saturated or unsaturated hydrocarbon radical; and

n is an integer of 1 to 4;

the molecular weight of the compound of formula (I) is about 500 or less;

a diamine chain extender; 1,3-bis(3-aminopropyl)tetramethyldisiloxane; 1,3-bis(4-aminobutyl)tetramethyldisiloxane; 1,4-butanediol; 1,2-ethylenediamine; ethanolamine; hexamethylenediamine; 1,4-butanediamine; water; 1,4-bis(4-hydroxybutyl)tetramethyldisiloxane; and combinations thereof.

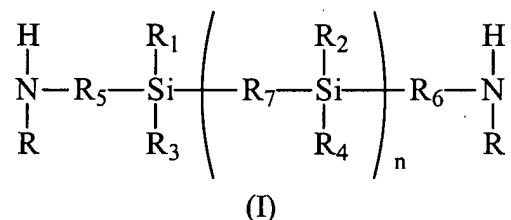
Claim 111 recites a polyurethane-urea elastomeric composition comprising a soft segment and a hard segment, wherein the soft segment is formed from:

(i) a macrodiol or a macrodiamine selected from the group consisting of a polysiloxane macrodiol, a polyether macrodiol, a polyester macrodiol, a polycarbonate macrodiol, a polyether macrodiamine, and mixtures thereof;

and wherein the hard segment is formed from:

(ii) a diisocyanate; and

(iii) a chain extender comprising a compound of formula (I):



wherein

R is hydrogen or an optionally substituted straight chain, branched or cyclic, saturated or unsaturated hydrocarbon radical;

R_1 , R_2 , R_3 , R_4 , R_5 and R_6 are each independently hydrogen or an optionally substituted straight chain, branched or cyclic, saturated or unsaturated hydrocarbon radical;

R_7 is a divalent linking group or an optionally substituted straight chain, branched or

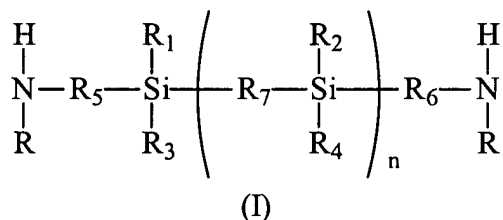
cyclic, saturated or unsaturated hydrocarbon radical; and

n is an integer of 1 to 4; and

the compound of formula (I) has a molecular weight of about 500 or less.

Claim 112 recites a polyurethane-urea elastomeric composition comprising a soft segment and a hard segment, wherein the soft segment is formed from:

- (i) a macrodiol comprising a polysiloxane macrodiol and a polycarbonate macrodiol; and the hard segment is formed from:
- (ii) a diisocyanate; and
- (iii) chain extender selected from the group consisting of a compound of formula (I):



wherein

R is hydrogen or an optionally substituted straight chain, branched or cyclic, saturated or unsaturated hydrocarbon radical;

R₁, R₂, R₃, R₄, R₅ and R₆ are each independently hydrogen or an optionally substituted straight chain, branched or cyclic, saturated or unsaturated hydrocarbon radical;

R₇ is a divalent linking group or an optionally substituted straight chain, branched or cyclic, saturated or unsaturated hydrocarbon radical; and

n is an integer of 1 to 4; and

the compound of formula (I) has a molecular weight of about 500 or less;

a diamine chain extender; 1,3-bis(3-aminopropyl)tetramethyldisiloxane; 1,3-bis(4-aminobutyl)tetramethyldisiloxane; 1,4-butanediol; 1,2-ethylenediamine; ethanolamine; hexamethylenediamine; 1,4-butanediamine; water 1,4-bis(4-hydroxybutyl)tetramethyldisiloxane;

and combinations thereof;

wherein the level of hard segment in the composition is about 21.8 wt.% to about 60 wt.%.

Claim 117 recites a biomaterial that is manufactured from a composition of claim 63.

Claim 118 recites a medical device, article or implant composed wholly or partly of the composition of claim 63.

Claim 120 recites a device or article composed wholly or partly of the composition of claim 63.

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the Examiner does not establish a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness. M.P.E.P. §2142. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Second, there must be some suggestion or motivation in the references or in the knowledge generally available to one of ordinary skill in the art to modify a reference or to combine reference teachings to arrive at the claimed invention. Third, there must be reasonable expectation of success. M.P.E.P. § 2142.

Neither Szycher et al. (U.S. 5,863,627); WO 98/13405; JP 4-248826; Li et al. (U.S. 5,221,724); and Ohtaki et al. (U.S. 5,861,085), alone or in combination, disclose or suggest all of the limitations of the presently claimed invention. Specifically, none of these references disclose or suggest the use of a compound of formula (I) as a chain extender. Additionally, JP 4-248826 teaches away from the presently claimed invention. Specifically, JP 4-248826 discloses that polymers not including the tertiary amino group-containing polyether polyol and not quaternized and treated with heparin are inferior to those that do, and should be avoided.

It is respectfully submitted that the Examiner has not met the burden to establish a *prima facie* case of obviousness. Applicant respectfully requests withdrawal of the rejection of the present claims under 35 U.S.C. § 103(a).

Conclusion

Applicants respectfully submit that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney (612-359-3261) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, Washington, D.C. 20231, on this 28 day of March, 2002.

Candy B. Buending

Name


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